K094039
Pg. 1 of 2

ATTACHMENT 2

510(k) SUMMARY

510(k) Owner:	Fidia Farmaceutici, S.p.A. Via Ponte dell Fabbrica 3/A 35031 Abano Terme PADOVA, ITALY	
	Contact: Dr. Giusi LoCastro Regulatory Affairs Phone: +39-049-8232906 Fax: + 39-049-8232398	MAY - 7 2010
Date Summary Prepared:	May 4, 2010	
Device:	Trade Name:	HYALO GYN®
	Common/Classification Name:	Lubricant, Patient, Vaginal, Latex Compatibile Product Code NUC
	Classification:	21 C.F.R. § 884.5300
Predicate Device:	Glycerin & Paraben Free Astroglide Biofilm, Inc. K072647	

Device Description:

HYALO GYN is a colorless, odorless, transparent, aqueous, hydrating gel that contains "Hydeal-D®" (a partial benzyl ester of hyaluronic acid), propylene glycol, a carbomer, preservatives (methyl-p-hydroxybenzoate and propyl-p-hydroxybenzoate), and sodium hydroxide (to balance the pH). The hyaluronic acid is manufactured using a bacterial fermentation process. HYALO GYN is intended for use as a personal lubricant. HYALO GYN is compatible with latex condoms: lubricated/non-lubricated latex, lubricated polyurethane, lubricated natural skin. HYALO GYN has a pH of 5.5-6.5 and a shelf life of 3 years.

HYALO GYN acts as a moisturizer and lubricant because of the strong hydrating properties of its hyaluronic acid derivative component. The carbomer and propylene glycol, combined with the hyaluronic acid derivative, enable HYALO GYN to achieve its thick, viscous gel form, and the mucoadhesive properties of the product allow it to adhere to the vaginal mucosa, enhancing the residence time, thus hydrating and protecting this tissue.

Intended Use:	Hyalo Gyn is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with condoms: lubricated/non-lubricated latex, lubricated polyurethane, lubricated natural skin.
Technological Characteristics:	HYALO GYN is substantially equivalent to the predicate device with regard to intended use and technological characteristics. Hydeal-D has been used in legally marketed devices, and no new questions of safety or effectiveness are presented. In addition, the other components (carbomer, propylene glycol, preservatives, and water) meet the specifications defined in the United States Pharmacopoeia (USP) or National Formulary (NF), where applicable.
Biocompatibility Data	Cytotoxicity studies demonstrate that HYALO GYN is not cytotoxic. An acute intraperitoneal toxicity study on HYALO GYN indicated that the lethal dose is >10 ml/kg but <20 ml/kg. A skin sensitization study provides evidence for the lack of a sensitizing effect. Vaginal tolerance testing demonstrated that HYALO GYN is a minimal vaginal irritant in the rabbit model.
Performance Data -- Nonclinical	Condom compatibility testing demonstrates that HYALO GYN is compatible with latex, polyurethane, and natural skin condoms. No macroscopic signs and no statistically significant differences were observed in tensile strength, elongation at break, and breaking force between treated and non-treated groups of condoms. Stability studies conducted in accordance with the ICH Q1A guidelines confirm a shelf-life of 36 months.
Performance Data -- Clinical	A pilot, open, uncontrolled clinical study was conducted in Italy to assess the safety and effectiveness of HYALO GYN. A total of 80 women were enrolled at a single site. They were instructed to use the test product every three days for 30 days. Follow-up visits were performed on Days 7 and 21, with the final visit taking place three days after the last application of test product. The results obtained in this study demonstrated that the test material had moisturizing effects on the vaginal mucosa. Safety was considered to be excellent as demonstrated by the absence of adverse events and the investigator's overall assessment of tolerability score (98.7%). There were no alterations of the vaginal ecosystem.
Conclusions	Based on the biocompatibility testing, nonclinical performance testing, and the clinical data provided in this 510(k), it is concluded that HYALO GYN is safe and effective as a vaginal lubricant and moisturizer, and at least as safe and effective as legally marketed vaginal lubricants. Further, the lack of adverse events reported over 8 years of postmarket experience with HYALO GYN outside of the U.S. demonstrate the safe and effective use of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAY - 7 2010

Fidia Farmaceutici S.p.A
% Sharon A. Segal, Ph.D.
Director of Regulatory Science
Morgan, Lewis & Bockius, LLP
1111 Pennsylvania Avenue, N.W.
WASHINGTON DC 20004

Re: K094039
Trade Name: HYALO GYN®
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: April 7, 2010
Received: April 7, 2010

Dear Dr. Segal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K094039

Device Name: HYALO GYN®

Indications for Use: HYALO GYN is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. This product is compatible with condoms: lubricated/non-lubricated latex, lubricated polyurethane, lubricated natural skin.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K094039